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Outcome and Quality of Life of Patients with Severe Chronic Limb Ischaemia: A Cohort Study on the Influence of Diabetes

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Objective: *To determine the influence of diabetes on the use of arterial reconstruction, the rate of amputation and death, and the quality of life of patients with severe limb ischaemia.*
Design: *A prospective study of patients with the first episode of ischaemia.*
Setting: *University tertiary referral centre.*
Methods: *Thirty-seven patients with diabetes and 50 without diabetes, were studied over a 12 month period with complete follow-up.*
Main outcome measures: *The proportion of patients undergoing an arterial reconstruction, amputation rate, death rate, and quality-of-life scores.*
Results: *Patients with diabetes underwent an arterial reconstruction less often than patients without diabetes (7/37 vs. 18/50). The odds of patients with diabetes having a higher incidence of adverse outcome was 1666:1 for minor amputation, 26:1 for major amputation, and 4.7:1 for death. There was a tendency towards a lower quality of life for patients with diabetes at 3 (OR 1.94, p = 0.036), 6 (OR 1.58, p = 0.117), and 12 (OR 1.47, p = 0.185) months.*
Conclusions: *In patients with diabetes, (1) the opportunity of undergoing an arterial reconstruction is lower, (2) morbidity and mortality are higher, and (3) the quality of life tends to be worse.*

Introduction

Diabetes mellitus has been associated with a high incidence of adverse outcome in follow-up studies of patients with intermittent claudication.[1,2] Similar investigations of individuals with severe limb ischaemia have been rare,[3,4] probably because a major amputation or an arterial reconstruction is often required. Although diabetes has also been associated with a worse prognosis after a major amputation,[5–7] better or comparable patency rates for infrainguinal bypass grafts have been reported for patients with this disease.[8–12] A possible explanation for this unexpected finding may be that an arterial reconstruction is used less often or more selectively in this group of patients.[3] Therefore, the possibility of a selection bias in surgical decision-making needs to be considered. To reduce bias of this type in studies on prognosis, it is necessary to adopt a prospective strategy, to include individuals before the mode of treatment is selected, and to consider treatments other than arterial reconstruction. In such a study, the outcome measures should include amputation and death rates but not graft patencies, since the latter are usable only in the subset of patients undergoing arterial reconstruction. In addition, an assessment of quality of life is also important when studying patients with either diabetes[13,14] or arterial occlusive disease.[15,16] For these reasons, we decided to conduct this prospective study on severe limb ischaemia with the principal aim of determining the influence of diabetes mellitus on (1) the use of an arterial reconstruction, (2) the incidence of adverse outcome, and (3) the quality of life.

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Material and Methods

Study design

A cohort design was used to reduce selection bias, evaluate multiple outcomes, determine incidence rates, and assess the quality of life according to a standardised follow-up. The 12 month period of observation was considered adequate to achieve stable results in terms of limb salvage, rehabilitation, quality of life, and cost.[3–5, 16–18] The patients were recruited

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consecutively from both the Outpatient Clinics and the Emergency Department of a public university hospital from January 2 to August 31, 1989. Zero time was the date of the first assessment of quality of life, before any treatment was selected.

Inclusion criteria

Based on the following criteria, 87 patients were admitted to the study: (1) age of 40 years or more, (2) palpable femoral but absent pedal pulses, (3) presence of rest pain, non-healing ulceration or gangrene, (4) no previous episode of severe ischaemia in either the affected or the contralateral limb, and (5) absence of cancer or mental disorders.

Exposure and outcome variables

The exposure variable was diabetes mellitus. A previous diagnosis of diabetes was accepted unless evidence to the contrary was subsequently found. A fasting blood glucose level of 140 mg/100 ml or higher was also a criterion for the diagnosis.

Minor and major amputation and death were the endpoints used in survival analysis. The proportion of patients undergoing an arterial reconstruction and the quality of life were also determined.

Patients

Fifty patients did not have diabetes mellitus (NDM group), while 37 did (DM group). Of the latter, 36 had type 2 diabetes and one had type 1 diabetes. The prevalence rate of 42% for diabetes was compatible with the findings of two other series at our institution, namely, 38% for 112 infrapopliteal bypasses[19] and 40% for 167 major amputations.[20] The high prevalence of diabetes in this study was probably a result of the referral pattern. On the other hand, only 47 (20 DM, 27 NDM) patients fulfilled the definition of critical leg ischaemia.[21] This corresponds to a prevalence rate of 54% in each group, in agreement with a recently reported rate of 51%.[22] Also of importance, gender, history of smoking, hypertension, and contralateral disease were unequally distributed in both groups (Table 1).

Table 1. Comparison of the cohorts at baseline

	With diabetes ($n=37$)	Without diabetes ($n=50$)
Age (years)		
Median	69	62
Interquartile range	60–73	54–69
Men	17	42
Caucasians	30	42
Smokers	14	40
Hypertension	20	12
Heart disease	23	22
Cerebral ischaemia	10	9
Rest pain only	2	8
Infected lesion	20	21
Critical ischaemia	20	27
Contralateral disease	26	17
Serum creatinine >1.4 mg/100 ml	13	8

Initial treatment

The initial treatment, that adopted within 60 days of time zero, was classified as conservative, arterial reconstruction or major amputation. The first of these comprised non-surgical treatment: lumbar sympathectomy, debridement, peripheral nerve crushing, and toe or transmetatarsal amputation. Arterial reconstruction consisted of endarterectomy or bypass grafting in the affected limb, whereas major amputation was either below (BK), through (TK) or above (AK) the knee.

Quality of life

We selected the Spitzer's QL-INDEX[23] which includes five domains of quality of life: (1) Involvement in Own Occupation (Occupation), (2) Activities of The Daily Living (Daily Living), (3) Perception of Own Health (Health), (4) Support of Family and Friends (Support), and (5) Outlook on Life (Outlook). The timeframe for this tool is the week previous to examination and each domain is scored zero, 1 or 2 so that the highest attainable score is 10. Although self-assessment has been recommended,[24–27] we did not use this method because of the limitations posed by old age, low literacy and either potential or actual visual loss. In addition, we also considered the advantages of using an interviewer (maximal response rate, no missing items, and minimal errors of misunderstanding).[28] The first author (ACF) assessed all the 87 patients during 321 medical interviews in a 100% complete follow-up. Although not a blinded observer, this author was uninvolved in patient care. The last score of quality of life obtained before death was used at all

the subsequent points in time in which a reassessment had been planned, as described by Cox *et al.*[24] (Strategy I). However, a second strategy was also adopted in which only the patients still alive were considered (Strategy II).

Statistical analyses

The use of an arterial reconstruction was analysed with standard methods for contingency tables. In the survival analysis, exponential survival models were considered using the prior-to-posterior Bayesian operation.[29,30] The posterior survival rates for the two groups were estimated. The probability that the DM group had a failure rate higher than that of the NDM group was evaluated. We represented these posterior probability values by pp-values and called the ratio pp/(1–pp) the Bayes factor. The prior distribution considered here is the uniform non-informative prior. The Mann-Whitney test and the generalised procedure of Morton and Dobson[31] were used for analysing the quality-of-life data. Partitioning of the QL-INDEX into its individual components was performed to show variations in each item. Stratification was undertaken to investigate the confounding effect of gender and history of smoking. Because of a strong association with both hypertension and contralateral disease, the confounding effect of these variables was probably partially corrected. Confidence intervals and *p*-values were used in the analyses of quality of life, although they have been omitted for convenience in some Tables.

Results

Use of an arterial reconstruction

Thirty (13 DM, 17 NDM) patients received only conservative treatment while 25 (7 DM, 18 NDM) patients underwent an arterial reconstruction and the remaining 32 (17 DM, 15 NDM) had a major amputation. Thus, the proportion of patients undergoing arterial reconstruction was 19% for DM and 36% for NDM. Although there was a trend towards lower reconstruction rates in diabetes, this was not statistically significant (Chi square = 2.25, d.f. = 1, 95% CI 4% to 34%, $p = 0.133$).

Survival analyses for limb and life events

There were 60 (29DM, 31 NDM) minor amputations, 43 (21 DM, 22NDM) major amputations, and 13 (7 DM, 6NDM) deaths, corresponding to a relative risk of 2.32, 1.72, and 1.65, respectively. The probability that the failure rate was higher in the DM population of patients with severe limb ischaemia was pp > 0.9994 for minor amputation, pp > 0.9634 for major amputation, and pp > 0.8235 for death. These results are shown in more detail in Table 2.

Quality of life

The quality of life at baseline was nearly the same in both the cohorts, with an OR of 0.93 (Table 3). With strategy I, the difference in favour of NDM patients was statistically significant at three months (OR) 1.94, $p = 0.036$), but not at 6 (OR 1.58, $p = 0.117$) or 12 (OR 1.47, $p = 0.185$) months. With strategy II, the advantage of NDM patients was smaller and not significant (Table 3).

The breakdown of the global scores of the QL-INDEX into the five primary domains yielded odds ratios higher than 1.00 (Table 4). A comparison of the 12 month quality of life taking into account the ultimate state of the affected limb, showed an

Table 2. Survival analyses for limb and life events

	DM patients (*n*=37)		NDM patients (*n*=50)				
	Events	X	Events	Y	RR	pp	Bayes factor pp/(1-pp)
A. Loss of the toes	29	3435	31	8506	2.32	0.9994	1665.667
B. Loss of the foot	21	6115	22	10995	1.72	0.9634	26.322
C. Death	7	11873	6	16780	1.65	0.8235	4.666

DM patients (17 men, 20 women).
NDM patients (42 men, 8 women).
X and Y are the total of person-days.
RR is the observed relative risk.
pp refers to the posterior probability.

Table 3. Scores of quality of life at baseline and over a 12 month follow-up under two strategies

		Baseline		3 months		6 months		12 months	
Score	Diabetes	Yes	No	Yes	No	Yes	No	Yes	No
Deaths		0	0	3 (0)	3 (0)	4 (0)	4(0)	7(0)	6 (0)
1		0	0	1	0	0	0	0	0
2		4	9	3 (4)	5	5 (6)	2	1 (4)	2
3		12	14	3 (4)	1 (2)	1 (2)	3 (5)	3 (4)	4 (6)
4		13	13	13 (14)	13 (14)	9 (11)	10 (11)	8 (11)	8 (10)
5		6	10	7	10 (11)	4	9 (10)	3	9 (10)
6		2	3	6	10	5	4	3	5
7		0	1	0	4	4	5	7	4
8		0	0	0	2	3	6	5	6
9		0	0	0	1	1	3	0	4
10		0	0	1	1	1	4	0	2 (3)
Strategy I									
Chi square		0.007		4.394		2.450		1.757	
p-value		0.933		0.036		0.117		0.185	
OR		0.97		1.94		1.58		1.47	
95% CI		0.47–1.98		1.04–3.60		0.89–2.80		0.83–2.60	
Strategy II									
Chi square		0.007		3.632		1.928		0.310	
p-value		0.933		0.057		0.16		0.58	
OR		0.97		1.87		1.53		1.19	
95% CI		0.47–1.98		0.98–3.56		0.84–2.79		0.64–2.19	

Values between parentheses are those used with strategy I.

Table 4. Breakdown of the QL-INDEX into its five primary domains using scores obtained under strategy I

	Time (months)	Baseline		3 months		6 months		12 months	
A. Occupation									
Diabetes		Yes	No	Yes	No	Yes	No	Yes	No
Points	0	31	43	31	36	28	31	29	33
	1	6	7	5	11	8	14	8	13
	2	0	0	1	3	1	5	0	4
OR		0.84		1.98		1.95		1.99	
B. Daily living									
Diabetes		Yes	No	Yes	No	Yes	No	Yes	No
Points	0	21	25	20	19	18	18	17	18
	1	16	24	16	26	16	21	20	22
	2	0	1	1	5	3	11	0	10
OR		1.35		2.00		1.86		2.07	
C. Health									
Diabetes		Yes	No	Yes	No	Yes	No	Yes	No
Points	0	16	17	7	6	6	4	6	3
	1	20	33	27	36	17	28	16	28
	2	1	0	3	8	14	18	15	19
OR		1.35		1.82		1.13		1.14	
D. Support									
Diabetes		Yes	No	Yes	No	Yes	No	Yes	No
Points	0	1	1	2	0	2	0	2	0
	1	5	10	1	4	1	1	1	1
	2	31	39	34	46	34	49	34	49
OR		0.70		1.07		4.38		4.38	
E. Outlook									
Diabetes		Yes	No	Yes	No	Yes	No	Yes	No
Points	0	10	17	8	5	7	4	7	5
	1	27	33	27	41	25	35	20	28
	2	0	0	2	4	5	11	10	17
OR		0.72		2.06		2.02		1.52	

None of the differences were statistically significant.

Table 5. Twelve-month quality of life according to the ultimate state of the limb

	No major amputation		BK or TK amputation		AK amputation	
Score Diabetes	Yes	No	Yes	No	Yes	No
Deaths	6	3	0	2	1	1
2	0 (2)	0	0	2	2	0
3	0 (1)	1 (2)	2	3	1	0 (1)
4	1 (4)	1	3	4 (6)	4	3
5	1	6 (7)	2	3	0	0
6	2	3	1	2	0	0
7	4	3	3	1	0	0
8	5	6	0	0	0	0
9	0	4	0	0	0	0
10	0	2 (3)	0	0	0	0
Strategy I						
Chi square	3.058		1.694		0.594	
p-value	0.080		0.193		0.441	
OR	2.01		0.47		2.75	
95% CI	0.92–4.39		0.15–1.46		0.21–36.02	
Strategy II						
Chi square	0.067		1.481		1.125	
p-value	0.796		0.223		0.289	
OR	1.13		0.49		—	
95% CI	0.45–2.80		0.16–1.54		—	

Values between parentheses are those used with strategy I.

increased risk for DM persons in both the subgroup with no major amputation (19 DM, 29 NDM) and the subgroup with an AK amputation (7 DM, 4 NDM), but not in that with a BK amputation (11 DM, 17 NDM), as shown in Table 5.

Stratification by gender and history of smoking revealed that the increased risk for both a minor amputation and a worse quality of life in DM patients was unconfounded. However, there were variations in risk in opposite directions for both major amputation and death (Table 6).

Table 6. Stratified analysis of minor and major amputation, death, and quality of life

	Men		Women	
	Smoker	Nonsmoker	Smoker	Nonsmoker
A. Minor amputation	1.61	2.77	5.23	1.87
B. Major amputation	0.78	1.97	...	0.75
C. Death	3.37	3.96	...	0.15
D. Quality of life				
Baseline	0.85	1.00	0.83	1.71
3 months	3.38	1.37	8.00	1.27
6 months	1.20	2.13	7.40	2.50
12 months	0.75	4.00	2.00	2.83

Values are stratum-specific relative risks (A, B and C) or odds ratios (D).

Discussion

The results of this study indicate that DM patients undergo arterial reconstruction less often than NDM patients, with a difference of 17% and a relative decrease of 47%. An even greater difference of 29% (14% DM, 43% NDM) has been reported by others.[3] These differences are large enough to suggest that arterial reconstruction is considered with more care in DM patients than it is in NDM patients. If this is so, a selection bias is introduced in studies comparing the results of arterial reconstruction in these groups. For this reason, the possibility of a selection bias must be seriously considered before accepting the better or comparable results for DM patients in some series of infrainguinal reconstruction.[8–12] Indeed, certain sources of bias in these studies are readily apparent as is the case for demographic variables,[12] surgical indication,[12] type of bypass,[9,10] and distal anastomosis sites.[8,10–12] Other problems include confounding by the use of tobacco[10] and undue confidence in subgroup analysis.[8,10]

Under the Bayesian rationale, we believe that the probability of a minor amputation in the population of DM patients far exceeds that of the NDM population (Bayes factor 1666:1). Such a striking difference between DM and NDM patients would hardly be a result of confounding, as confirmed by a stratum-specific odds ratio ranging from 1.61 to 5.23 (Table 6). The difference was less impressive for a major amputation (Bayes factor 26:1). Consistent with this interpretation, the relative risk was lower than 1.00 in two strata (Table 6). This is an indication of confounding. However, a worse prognosis for the limb in DM patients has been widely reported.[1,3–7,32,33] Although the present study was too short in duration to confidently assess death rates, we found a slightly increased risk for DM patients, as expected.[3,5] Chance is the best explanation for the disparities found with stratification for this latter variable (Table 6).

The quality of life scores were higher for NDM patients in all three assessments made during the follow-up. The stratum-specific odds ratios greater than 1.00 in 11 out of 12 follow-up measures indicate absence of confounding. Although difficult to ascertain on clinical grounds, some supportive evidence in favour of the relevance of the differences in quality of life was provided by the partitioning of the QL-INDEX scores. This showed that all the five domains were scored higher in NDM patients, with no change in opposite direction that could mislead the summed scores.[24] In our opinion, this result is an indication of the strengths of the QL-INDEX in the setting of limb

ischaemia. With regard to the individual domains, the high number of patients scoring zero for occupation is in agreement with the idea that it should be replaced by Mobility in order to improve the QL-INDEX.[34,35] The insensitivity to change identified for Support[34] was also confirmed. On the contrary, the readily apparent improvement with time for Daily Living, Health and Outlook reflects a good sensitivity to change (Table 4).

As expected, quality of life scores were the highest for patients who did not have a major amputation, intermediate for those with either a BK or a TK amputation, and lowest in the subgroup having an AK amputation. These differences are a further indication of the adequacy of the QL-INDEX as an outcome measure in this study. Although a better quality of life was found for DM patients with a BK or a TK amputation, this was probably a result of small subgroup sizes.

The probabilities under the rationale of Bayesian inference support our believe that adverse outcomes are more frequent in DM patients. In addition, the difference in quality of life according to the usual frequentist principles was also less favourable to these patients. Our conclusions are that in DM patients: (1) the opportunity of undergoing an arterial reconstruction is lower, (2) morbidity and mortality are higher, and (3) the quality of life tends to be worse.

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